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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,410	04/12/2001	Toyohiro Sawada	019941-000510US	3651

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/24/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,410

Applicant(s)

SAWADA ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8 and 10-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8 and 10-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Acknowledgment of Papers Received: Notice of Appeal filed 8/15/03 and Amendment dated 8/15/03.

After consideration of the amendment after final, finality has been removed and the following is a new action.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 3-8, 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al (USPN 5,425,950) in combination with Nakashima et al (EP 0 661 045) in view of Taniguchi et al (EP 0 709 386) both in further view of Wong et al (USPN 5,391,381) and Kawata et al (USPN 4,404,183). The claims are drawn to a compressed-coated tablet. The tablet's core comprises fillers and an active agent. The outer layers comprise a hydrogel-forming polymer. The active agent is recited as CYP3A4. The fillers are well known in the art (sucrose,

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lactulose, polyethylene glycol, etc.). The hydrogel forming polymers are equally well known in the art.

4. Dandiker et al teaches a compressed coated tablet where the core comprises fillers, which can erode, along with active agents (col. 6, lin. 15 – 24). Sucrose starch, and other common erodible fillers are listed (col. 5, lin. 48 – 50). The outer layer comprises hydrogel-forming polymers (examples). The reference does not disclose that the filler erodes 40-90%, yet the claims do not state a time frame for this erosion. Any known filler will erode 40-90% in the digestive tract given enough time. No indication is given in the claims or throughout the specification that the filler has been modified in anyway as to render it only erodible to this percentage. It can be concluded that any filler would erode tot his percentage given enough time in the digestive tract. Barring an inclusion of a time frame or dissolution profile, the limitation to the percentage of erosion of the filler, cannot be given patentable weight.

Nakashima discloses a compression-molded tablet comprising a hydrogel-forming polymer and a hydrophilic base. The tablet of Nakashima also contains a drug. The disclosure recites various drugs ranging from anti-inflammatory agents to central nervous system drugs such as idebenone. Also the tablet is formulated to release or be absorbed in the lower digestive system (pg. 3, lin. 25 – 35). Polyethylene glycol and polyethylene oxide are used as the hydrophilic base/hydrogel-forming polymer used in the tablet of Nakashima (Examples). The outer coating has viscosity and molecular weight specification, which meet those of applicant's claims.

Taniguchi discloses a fused benzazepine derivative, which can be useful as a vasopressin antagonist. The drug can be formulated into tablets using conventional excipients such as

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sucrose, gelatin and hydroxypropylcellulose (pg. 27, lin. 23 – 37). The drug of the invention can be used in the treatment of various disorders ranging from cerebrovascular disease to renal disorders (pg. 23, lin. 24 – 44).

Wong shows the level of skill in the art that is known to combine tablets delivering active agents comprising polyethylene and red ferric oxide (Examples).

Kawata, et al provides evidence to the level of skill in the art to combine and use such excipients in coated tablets similar to that of the invention. Fillers such as polyethylene glycol and citric acid (col. 1, lin. 44 – 65) are used in the tablet of the invention.

In view of the prior art one of ordinary skill in the art would have been motivated to combine the compressed coated tablet of Dandiker with the hydrogel-forming polymer of Nakashima. Dandiker suggests that the outer later of the compressed-coated tablet comprise polyethylene glycol and other hydrogel-forming polymers. The coating of Nakashima comprises polyethylene glycol and other hydrogel forming polymers. The polymer is optimal for a timed-release delivery in the digestive tract, since the coating is formulated to allow the center to erode slowly as the unit passes over though the GI tract. A skilled artisan would have followed the suggestions of Dandiker to compression coat the tablet with a hydrogel-forming polymer and use the polymer of Nakashima to do so. A skilled artisan would have been motivated to combine the hydrophilic base/hydrogel-forming polymer preparation with the drug of Taniguchi in order to provide a sustained release profile for the drug to the lower intestinal tract. Following the knowledge on the art the skilled artisan could have substituted any number of excipients including those of Wong or Kawata into the preparation in order to add an aesthetic appeal or better erosion properties. It would have been obvious to one of ordinary skill in the art, at the

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time of the invention to combine these teachings and suggestion in this way, with an expected result of sustained release oral tablet capable of treating various renal and cardiovascular disorders.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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